IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
Re: Appeal to the Board of Patent Appeals and Interferences

Appellants	Wei et al.	)	Examiner:	Jacqueline A. DiRamio
Serial Number:	10/718,997	)	Group Art Unit:	1641
Filed:	November 21, 2003	)	Customer Number:	22827
Confirmation No:	9089	)	Deposit Account:	04-1403
Title:	Extension of the Dynamic Detection Range of Assay Devices	)	Attorney Docket No.	KCX-691 (18379)

1. ☐ **NOTICE OF APPEAL**: Pursuant to 37 CFR 41.31, Applicant hereby appeals to the Board of Appeals from the decision dated ________________ of the Examiner twice/finally rejecting claims _____________.
2. ☒ **BRIEF** on appeal in this application pursuant to 37 CFR 41.37 is transmitted herewith (1 copy).
3. ☐ An **ORAL HEARING** is respectfully requested under 37 CFR 41.47 (due within two months after Examiner's Answer).
4. ☐ Reply Brief under 37 CFR 41.41(b) is transmitted herewith (1 copy).
5. ☐ "Small entity" verified statement filed: [ ] herewith [ ] previously.
6. **FEE CALCULATION:**

	Fees
If box 1 above is X'd enter $ 540.00	$ 0.00
If box 2 above is X'd enter $ 540.00	$ 540.00
If box 3 above is X'd enter $1,080.00	$ 0.00
If box 4 above is X-d enter –0- (no fee)	$ 0.00
PETITION is hereby made to extend the original due date of March 8, 2009, hereby made for an extension to cover the date this response is filed for which the requisite fee is enclosed (1 month $130; 2 months $490; 3 months $1,110; 4 months $1,730, 5 months $2,350	$ 0.00
SUBTOTAL:	$ 540.00
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Date: March 9, 2009

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(Signature of person transmitting documents)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application: Wei et al.	)	Examiner: Jacqueline A. DiRamio
Serial No: 10/718,997	)	Group Art Unit: 1641
Filed: November 21, 2003	)	Deposit Account No: 04-1403
Confirmation No: 9089	)	Customer No: 22827
Title: Extension of the Dynamic Detection Range of Assay Devices	)	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

BRIEF ON APPEAL

Appellants submit the following brief on appeal in accordance with 37 C.F.R. § 41.37:

1. REAL PARTY IN INTEREST

The real party in interest in this matter is the assignee of record, Kimberly-Clark Worldwide, Inc.

2. RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to the Appellants or the Appellants' legal representative which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

3. STATUS OF CLAIMS

Currently, claims 14-19 and 29-31 remain pending in the present application including independent claim 14. Claims 1-13 were previously cancelled from the present application and claims 20-28 were withdrawn. All pending claims are attached hereto in the Claims Appendix.

In the Final Office Action of August 6, 2008, claims 14-19 and 29-31 were finally rejected under *35 U.S.C. § 103(a)*.

The rejection of claims 14-19 and 29-31 is hereby appealed.

4. STATUS OF AMENDMENTS

All amendments have been entered into the record.

5. SUMMARY OF CLAIMED SUBJECT MATTER

In general, the present application is directed to an improved technique of reducing the "hook effect" and extending the dynamic range of an assay device. (*See e.g.*, Appl. p. 2, ll. 17-18). For example, independent claim 14 is directed to a flow-through assay device for detecting the presence or quantity of an analyte residing in a test sample. (*See e.g.*, Appl. p. 3, ll. 3-5). The flow-through assay device comprises a porous membrane in communication with optical detection probes conjugated with a first antibody specific for the analyte. (*See e.g.*, Appl. p. 3, ll. 5-7). The porous membrane defines a competitive zone that contains a second antibody immobilized on the porous membrane that is complexed to an antigen containing an optically detectable substance prior to the application of a test sample to the device. (*See e.g.*, Appl. p. 3, ll. 7-10). The antigen is identical to or an analog of the analyte and the optically detectable substance is capable of producing a competitive signal when contained

within the competitive zone. (*See e.g.*, Appl. p. 3, ll. 10-12). The porous membrane also defines a detection zone within which a third antibody is immobilized that is configured to bind to complexes formed between the analyte and the conjugated optical detection probes to produce a first detection signal. (*See e.g.*, Appl. p. 3, ll. 7-8 and 12-15). The third antibody is configured to bind to the antigen from the competitive zone to produce a second detection signal. (*See e.g.*, Appl. p. 3, ll. 15-16). The amount of the analyte within the test sample is determined from the competitive signal, and at least one of the first detection signal and the second detection signal. (*See e.g.*, Appl. p. 3, ll. 16-18).

To better understand what is required by the present claims, reference is made to Figs. 4-5 of the specification (portions of which are reproduced below), which illustrate one embodiment of the present claims.

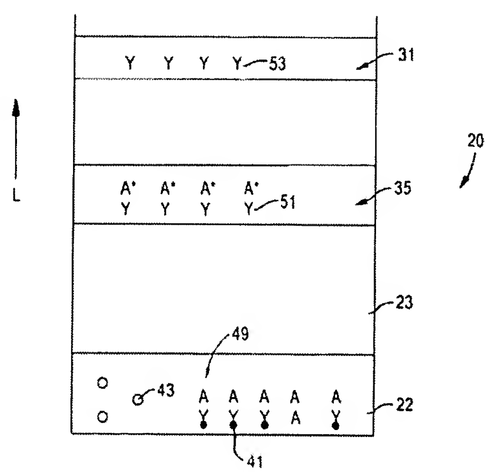

FIG. 4

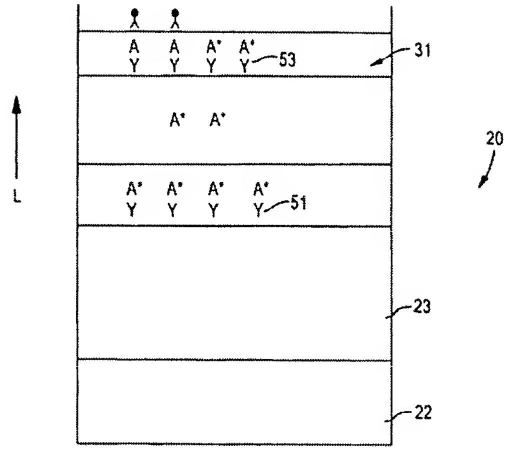

FIG. 5

As shown in Fig. 4, a test sample containing an antigen A travels in the direction "L" and mixes with fluorescent detection probes 41 conjugated with an antibody. (*See e.g.*, Appl. p. 18, ll. 6-10). The antigen A binds with the probes 41 to form analyte/conjugated probe complexes 49. (*See e.g.*, Appl. p. 18, ll. 19-21). Some of the antigen A remains free due to the limited availability of the probes 41. (*See e.g.*, Appl. p. 18, ll. 21-22). As shown in Fig. 5, the free antigen A and the complexes 49 then travel to the competitive zone 35, within which is immobilized an antibody 51 complexed to a labeled molecule A* that is identical in nature or an analog of the antigen A. (*See e.g.*, Appl. p. 18, ll. 22-25). Due to its smaller size, the free antigen A reaches the competitive zone 35 first, and competes with the molecule A* for the binding sites on the antibody 51. (*See e.g.*, Appl. p. 18, ll. 25-27). The complexes 49 and the displaced molecules A* travel on to the detection zone 31 and bind to an antibody 53. (*See e.g.*, Appl. p. 18, ll. 27-28). Once captured, the fluorescence signals of the labeled molecules A* and detection probes 41 may be measured at the detection zone 31 and the competitive zone 35. (*See e.g.*, Appl. p. 18, ll. 32-33; Appl. p. 19, l. 1).

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

I. Claims 14-18 and 29-31 stand rejected under *35 U.S.C. § 103(a)* as being unpatentable over U.S. Patent No. 7,144,742 to Boehringer, et al. in view of U.S. Patent No. 5,573,921 to Behnke, et al.[1]

II. Claim 19 stands rejected under *35 U.S.C. § 103(a)* as being unpatentable over U.S. Patent No. 7,144,742 to Boehringer, et al. in view of U.S. Patent No. 5,573,921 to Behnke, et al. and further in view of U.S. Patent Application Publication No. 2005/0196875 to Blatt, et al.

7. ARGUMENT

Appellants respectfully submit that the presently pending claims are patentable over the cited references and rejections.

I. Claims 14-18 and 29-31 are patentable over Boehringer, et al. in view of Behnke, et al.

Boehringer, et al. is directed to a solid phase specific binding lateral flow assay. An embodiment of the lateral flow device of Boehringer, et al. is shown in Fig. 1 (re-produced below).

[1] Polito, et al. (2004/0018637) and Harris, et al. (2003/0162236) were also cited in combination with these references to reject dependent claims 17 and 18. To simplify the issues for appeal, Appellants have not separately addressed these rejections. However, Appellants in no way acquiesce to these rejections, nor to the status of these references as prior art to the present application.

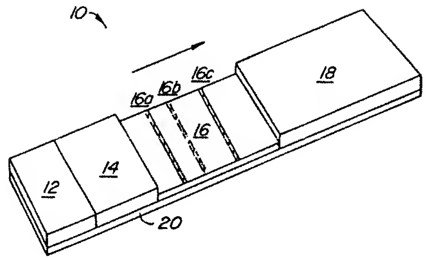

FIG. 1.

As shown, the device 10 contains a labeling zone 14, barrier zone 16a, and detection zones 16b and 16c. In the "competitive format" relied upon by the Examiner, the labeling zone 14 contains a labeled antigen (e.g., labeled analyte analog), the barrier zone 16a contains an antibody that is complementary to the analyte, and the detection zones contain a binding substance specific for the labeled antigen. When no analyte is present, the labeled antigen will bind to the antibody in the barrier zone 16a. As sample analyte concentration increases, the labeled antigen will compete with the analyte for the antibody in the barrier zone 16a. (Col. 11, ll. 1-31).

Behnke, et al. is directed to a process for determining a low-molecular weight pollutant in a test sample using a test strip. An embodiment of the test strip of Behnke, et al. is shown in Figs. 1a-1c (re-produced below).

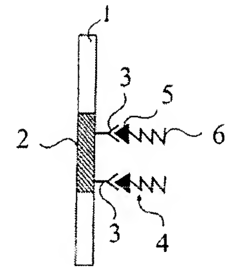

Fig. 1a

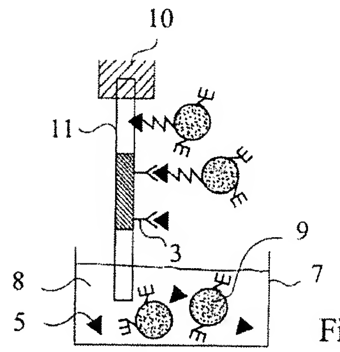

Fig. 1b

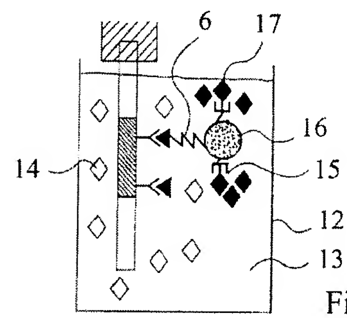

Fig. 1c

As shown, the test strip 1 includes antibody molecules 3 in a measurement area 2 and a tracer 4 that contains the analyte 5 and an appendage 6 (e.g., biotin) bound to the antibody molecules 3. When dipped into a test solution (Fig. 1b) containing the analyte 5 and reaction partner 9 (e.g., streptavidin-enzyme conjugate), each molecule of the analyte 5 can displace one tracer molecule 4. The displaced tracer 4 binds to the reaction partner 9 and migrates into an area 11 of the test strip located above the measurement area 2. The test strip 1 is then dipped into another vessel 12 containing a developing solution 13 (Fig. 1c). The solution 13 contains substrate molecules 14 that enter the test strip 1 and react to form a dye 17.

A. Independent claim 14 is patentable over Boehringer, et al. in view of Behnke, et al.

In rejecting claims under *35 U.S.C. § 103(a)*, it is incumbent upon the Examiner to establish a factual basis to support the legal conclusion of obviousness.[2] In so doing, the Examiner must make the factual determinations set forth in *Graham v John Deere Co.*[3] In the present case, the Examiner likened the competitive format of the "barrier zone 16a" of Boehringer, et al. to the "competitive zone" of independent claim 14. While the Examiner correctly notes that the barrier zone of Boehringer, et al. may employ an antibody, the competitive zone of independent claim 14 also requires an "antigen containing an optically detectable substance" that is "complexed to a second antibody." The Examiner admits that Boehringer, et al. fails to disclose these features. However, the Examiner states the following:

> [I]t would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Boehringer, et al. the binding of the antigen containing the optically detectable substance to the immobilized antibody of the barrier zone prior to application of the test sample as taught by Behnke et al. because Behnke et al. teach the benefit of binding an analyte analog attached to a dye to an immobilized antibody on a test strip prior to application of a test sample.

(p. 4 of the Final Office Action of Aug. 6, 2008).

Appellants disagree and submit that the Examiner erred in rejecting claims 14-18 and 29-31.

1. The proposed combination of Boehringer, et al. and Behnke, et al. fails to teach all of the limitations of Independent Claim 14

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[2] *See In re Fine*, 837 F.2d 1071, 1073, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988.

[3] 383 U.S. 1, 17, 148 USPQ 459, 467 (1966); *See also, In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992) (stating "the examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a prima facie case of unpatentability").

To establish a *prima facie* case of obviousness, in addition to other requirements, the cited references must teach or suggest all the claim limitations.[4] As indicated above, independent claim 14 requires a competitive zone that contains a second antibody complexed to an antigen containing an optically detectable substance prior to the application of a test sample to the device. The Examiner asserts that it would have been obvious to "pre-immobilize" a labeled antigen onto the barrier zone of Boehringer, et al. (Advisory Action, p. 2). Even if this were true, however, such a pre-immobilized antigen would not necessarily be "complexed" to the antibody, as is required by independent claim 14.

Further, independent claim 14 also requires optical detection probes conjugated with a first *antibody* specific for the analyte. In this manner, the antibody of the probes can bind to the analyte. In the competitive format of Boehringer, et al. relied upon by the Examiner, however, the "probes" are conjugated with an *antigen*. In this manner, the antigen of the probes compete – but do not bind – with the analyte for binding sites at the barrier zone.

2. One of ordinary skill in the art would not have combined the teachings of Behnke, et al. with the teachings of Boehringer, et al. as attempted by the Office Action.

In conducting an analysis under *§ 103(a)*, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.[5] Accordingly, even if all elements of a claim are disclosed in various prior art references, the claimed invention taken as a whole cannot be said to be obvious

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[4] *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

[5] *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 82 USPQ2d 1385, 1396 (2007); *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006).

without some reason given in the prior art why one of ordinary skill would have been prompted to modify the teachings of the references to arrive at the claimed invention.[6]

To the extent that the Examiner is attempting to combine the references by binding the antigen of Behnke, et al. to the immobilized antibody used in the barrier zone of Boehringer, et al., Appellants submit that such a combination is not obvious. Namely, the device achieved by such a combination would employ a labeled antigen as the "conjugated probes" and an antigen in the barrier zone. Of course, this would then mean that the analyte, probes, and barrier zone would all include an antigen. One of ordinary skill in the art would readily understand that such a format would not operate in the manner intended by Boehringer, et al. – if at all. Thus, for at least this reason, one of ordinary skill in the art would not have found it obvious to combine the references in this manner.

3. The Examiner's attempted modification of Boehringer, et al. is based on impermissible hindsight analysis.

To the extent that any motivation exists for modifying Boehringer, et al. as suggested by the Examiner, Appellants submit that it results only from using Appellants' disclosure as a blueprint to reconstruct the claimed invention out of isolated teachings in the prior art, which is improper hindsight analysis under *35 U.S.C. § 103 (a)*. The U.S. Supreme Court recently reaffirmed that a "factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of argument reliant upon ex post reasoning." *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 82 USPQ2d at 1397. *See also*, *Graham v. John Deere Co.*, 383 U.S. at 36, 148 USPQ at 474. Thus,

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[6] *See e.g.*, *In re Regel*, 188 U.S.P.Q. 132 (C.C.P.A. 1975).

Appellants respectfully submit that independent claim 14 patentably defines over the cited references.

B. The proposed combination of Boehringer, et al. and Behnke, et al. fails to teach all of the limitations of Dependent Claim 30

Claim 30 depends from independent claim 14 and further requires that the *conjugated detection probes bind to the antigen within the competitive zone to produce a second competitive signal when no analyte is present within the test sample.* (See e.g., Figs. 3A and 3B; Appl. pp. 19-21). According to the Examiner, the feature of claim 30 is satisfied by the competitive format of Boehringer, et al. As noted above, however, the barrier zone employed by Boehringer, et al. in the competitive format does not include an antigen containing an optically detectable substance that is complexed to a second antibody. Even if the barrier zone did somehow contain an antigen, the "conjugated detection probes" of Boehringer, et al. would not bind to this antigen because they themselves contain a labeled antigen.

C. The proposed combination of Boehringer, et al. and Behnke, et al. fails to teach all of the limitations of Dependent Claim 31

Claim 31 depends from independent claim 14 and further requires that the intensity of the first detection signal reaches a maximum value at or near the saturation concentration of the analyte within the test sample. (*See e.g.*, Figs. 3A and 3B; Appl. pp. 19-21). According to the Examiner, the feature of claim 31 is satisfied by the competitive format of Boehringer, et al. However, at the saturation concentration of the analyte in Boehringer, et al., only "some of the labeled antigen" evades capture at the barrier zone and flows to the detection zone. (Col. 11, ll. 32-35). Clearly, the intensity

of the detection signal is not at its maximum value at this point of the assay, as is required by claim 31.

II. Claim 19 is patentable over Boehringer, et al. in view of Behnke, et al. and further in view of Blatt, et al.

Claim 19 depends from independent claim 14 and requires that the amount of the analyte within the test sample is capable of being determined from one or both of the following formulae:

$$D_1 + x,$$
$$\text{when } x > 0,\ D_1 = D_{1max}$$

wherein,

$x = C_{1max} - C_1$;

C_{1max} is a predetermined maximum intensity for said competitive signal;

C_1 is the intensity of said competitive signal;

D_1 is the intensity of said first detection signal; and

D_{1max} is a predetermined maximum intensity for said first detection signal; or

$$D_1 + D_2,$$
$$\text{when } D_2 > 0,\ D_1 = D_{1max}$$

wherein,

D_1 is the intensity of said first detection signal;

D_{1max} is a predetermined maximum intensity for said first detection signal; and

D_2 is the intensity of said second detection signal.

The Examiner acknowledges that Boehringer, et al. and Behnke, et al. fail to disclose these features, but indicates that they would have been obvious based on the teachings of Blatt, et al.

Blatt, et al. was filed on April 19, 2004 and published on September 8, 2005. The present application, on the other hand, was filed on November, 21, 2003. Thus, Blatt, et al. is not prior art to the present application under any applicable section of *35 U.S.C. § 102*. For this reason alone, Appellants submit that claim 19 is patentable over the cited references.

In conclusion, Appellants request favorable action and allowance of the presently pending claims.

Respectfully requested,

DORITY & MANNING, P.A.

Date: March 9, 2009

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8. CLAIMS APPENDIX

1-13. (Cancelled)

14. (Rejected) A flow-through assay device for detecting the presence or quantity of an analyte residing in a test sample, said flow-through assay device comprising a porous membrane in communication with optical detection probes conjugated with a first antibody specific for the analyte, said porous membrane defining:

a competitive zone that contains a second antibody immobilized on said porous membrane that is complexed to an antigen containing an optically detectable substance prior to the application of a test sample to the device, said antigen being identical to or an analog of the analyte and said optically detectable substance being capable of producing a competitive signal when contained within said competitive zone; and

a detection zone within which a third antibody is immobilized that is configured to bind to complexes formed between the analyte and said conjugated optical detection probes to produce a first detection signal, said third antibody also being configured to bind to said antigen from said competitive zone to produce a second detection signal, wherein the amount of the analyte within the test sample is determined from said competitive signal, and at least one of said first detection signal and said second detection signal.

15. (Rejected) A flow-through assay device as defined in claim 14, wherein said optical detection probes and said optically detectable substance of said antigen each comprise a visual label.

16. (Rejected) A flow-through assay device as defined in claim 14, wherein said optical detection probes and said optically detectable substance of said antigen each comprise a luminescent compound.

17. (Rejected) A flow-through assay device as defined in claim 16, wherein said detection probes emit a signal at a different wavelength than said optically detectable substance of said antigen.

18. (Rejected) A flow-through assay device as defined in claim 14, wherein said porous membrane further defines a calibration zone that is configured to produce a calibration signal.

19. (Rejected) A flow-through assay device as defined in claim 14, wherein the amount of the analyte within the test sample is capable of being determined from one or both of the following formulae:

$$D_1 + x,$$
$$\text{when } x > 0,\ D_1 = D_{1max}$$

wherein,

$x = C_{1max} - C_1$;

C_{1max} is a predetermined maximum intensity for said competitive signal;

C_1 is the intensity of said competitive signal;

D_1 is the intensity of said first detection signal; and

D_{1max} is a predetermined maximum intensity for said first detection signal; or

$$D_1 + D_2,$$
$$\text{when } D_2 > 0,\ D_1 = D_{1max}$$

wherein,

D_1 is the intensity of said first detection signal;

D_{1max} is a predetermined maximum intensity for said first detection signal; and

D_2 is the intensity of said second detection signal.

20. (Withdrawn) A method for detecting the presence or quantity of an analyte residing in a test sample, said method comprising:

i) providing a flow-through assay device comprising a porous membrane in communication with detection probes conjugated with a first antibody specific for the analyte, said porous membrane defining:

a) a competitive zone within which is immobilized a second antibody complexed to an antigen containing an optically detectable substance, said antigen being identical to or an analog of the analyte and said optically detectable substance being capable of producing a competitive signal when contained within said competitive zone; and

b) a detection zone within which a third antibody is immobilized that is configured to bind to complexes formed between the analyte and said conjugated optical detection probes to produce a first detection signal, said third antibody also being configured to bind to said antigen from said competitive zone to produce a second detection signal;

ii) contacting a test sample containing the analyte with said conjugated detection probes;

iii) measuring the intensity of said competitive signal at said competitive zone, and the intensity of said first and second detection signals at said detection zone; and

iv) determining the amount of the analyte within the test sample from one or both of the following formulae:

$$D_1 + x,$$

$$\text{when } x > 0,\ D_1 = D_{1max}$$

wherein,

$x = C_{1max} - C_1$;

C_{1max} is a predetermined maximum intensity for said competitive signal;

C_1 is the intensity of said competitive signal;

D_1 is the intensity of said first detection signal; and

D_{1max} is a predetermined maximum intensity for said first detection signal; or

$$D_1 + D_2,$$

$$\text{when } D_2 > 0,\ D_1 = D_{1max}$$

wherein,

D_1 is the intensity of said first detection signal;

D_{1max} is a predetermined maximum intensity for said first detection signal; and

D_2 is the intensity of said second detection signal.

21. (Withdrawn) A method as defined in claim 20, wherein said optical detection probes and said optically detectable substance of said antigen each comprise a visual label.

22. (Withdrawn) A method as defined in claim 20, wherein said optical detection probes and said optically detectable substance of said antigen each comprise a luminescent compound.

23. (Withdrawn) A method as defined in claim 22, wherein said detection probes emit a signal at a different wavelength than said optically detectable substance of said antigen.

24. (Withdrawn) A method as defined in claim 20, further comprising exciting said conjugated optical detection probes at said detection zone to produce said first detection signal.

25. (Withdrawn) A method as defined in claim 24, further comprising exciting said optically detectable substance at said competitive zone to produce said competitive signal.

26. (Withdrawn) A method as defined in claim 25, further comprising exciting said optically detectable substance at said detection zone to produce said second detection signal.

27. (Withdrawn) A method as defined in claim 20, wherein said porous membrane further defines a calibration zone that is configured to produce a calibration signal.

28. (Withdrawn) A method as defined in claim 27, further comprising generating a calibration curve by plotting said competitive signal and said first and second detection signals as calibrated by said calibration signal for a plurality of predetermined analyte concentrations.

29. (Rejected) A flow-through assay device as defined in claim 14, wherein the intensity of the competitive signal is at a maximum value when no analyte is present within the test sample.

30. (Rejected) A flow-through assay device as defined in claim 14, wherein the conjugated detection probes bind to the antigen within the competitive zone to produce a second competitive signal when no analyte is present within the test sample.

31. (Rejected) A flow-through assay device as defined in claim 14, wherein the intensity of the first detection signal reaches a maximum value at or near the saturation concentration of the analyte within the test sample.

9. EVIDENCE APPENDIX

None

10. RELATED PROCEEDINGS APPENDIX

None